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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,337	07/10/2003	Kazuo Sakuma		5248

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Kazuo Sakuma
2119-1, Kaminayoro, Shimokawa-chou
Kamikawa-gun
Hokkaidou, 098-1216
JAPAN

EXAMINER	
DAVIS, RUTH A	
ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,337	SAKUMA, KAZUO	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because the abstract should be a single paragraph and should avoid legal phraseology used in patent claims (MPEP 608.01(b) C). The abstract should be combined into a single paragraph and the term "said" in lines 4 and 5 should be removed. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: The specification does not contain a brief description of figures 23 – 24. See MPEP 608.01(f).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for culturing Kabanoanatake, however are rendered vague and indefinite for reciting "and obtaining active ingredients" because it is unclear to what active ingredients applicant refers. It is unclear what is being obtained from the

culture method, such that one in the art would not be able to ascertain what the scope of the invention is. Since the method is drawn to a method for culturing Kabanoanatake, it is unclear if the active ingredient is the grown hyphae itself, or if the hyphae are further extracted to obtain an "active ingredient". The claims are further confusing because it is unclear if the method is truly drawn to a method for culturing Kabanoanatake, or to a method for obtaining an "active ingredient".

In claim 1, line 1, "The method" lacks sufficient antecedent basis. Applicant may prefer to change "The method" to "A method" to more clearly define the invention.

In claim 1, line 2, "the liquid medium" lacks sufficient antecedent basis.

In claim 1, it is unclear if applicant intends to include a Markush group as the proper language is not used, and it is unclear what may or may not be included in such a Markush group. Moreover, it is unclear if the medium must contain each of the recited carbon sources, starch, peptone, yeast extract, water and phosphate buffer, or if only at least one of the recited elements must be present.

Claim 1 is confusing for reciting "20 to 49 days and/or 100 days or longer", because it is unclear what length of time is required to practice the claimed method. Since applicant includes two separate limitations that may or may not be in the alterative, it is unclear as to the scope of the claimed method.

Claim 2 is rendered vague and indefinite because it is unclear if the active ingredient is composed of the recited elements, or if the medium is composed of the recited elements. The claim is further confusing for reciting "per Liter of the medium" in line 3, because if the medium

is composed of the recited elements, then it is confusing as to what is contained in the "Liter of the medium".

In claim 6, line 2, it is unclear if each of the recited limitations are in the alternative, or if each of the claimed constituents must be present in the medium.

Claim 9 is vague and indefinite because it is unclear if the method of claim 1 further consists of the claimed steps, or if the method rather consists of the claimed steps.

In claim 10, line 1, "said shake culture" lacks sufficient antecedent basis.

Claim 10 is vague and indefinite for reciting "such as a jar fermenter" because it is unclear if the shake culture must necessarily be a jar fermenter, or if the limitation is merely exemplary in what devices may be used in shake culture. Moreover, it is unclear if the method must use a jar fermenter or any other device to achieve the shake culture.

Claim 11 is vague and indefinite because it is unclear if the method of claim 1 further consists of the claimed steps, or if the method rather consists of the claimed steps.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4 – 6, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuma (WO 94/38473).

Applicant claims a method for culturing Kabanoanatake in liquid, the method consisting of inoculating seed fungi from cultured Kabanoanatake in a liquid medium; wherein the medium contains a mixture of malt, glucose, saccharose or starch, peptone, yeast extract, water and phosphate buffer; and incubating the culture at 20 – 30C for 20 – 49 days, or 100 or more days; and obtaining active ingredients from the hyphae or medium. The method alternatively uses white birch sap is used instead of or in addition to water in the medium; the medium further contains one or more wood constituents which are selected from a disclosed group. The method further comprises determining the time of formation of active ingredients, based on culture color, protein amounts in the medium, decrease in carbon sources, pH of the medium; and collecting the active ingredients. Finally, the method further comprises exposing growing hyphae to light.

Sakuma teaches a method for culturing Fuscoporia oblique (Kabanoanatake), the method comprising inoculating Fuscoporia into a liquid medium comprising malt, glucose, saccharose, starch, peptone, yeast extract, water, and phosphate buffer, white birch saw dust (or wood constituents) (Culture Improvements). The hyphae and/or medium were then extracted for active ingredients (culture improvements). Sakuma teaches that culturing of Fuscoporia is optimal at 13 – 30C for up to 4 months (Artificial Culture of the Hypha of F. oblique). Sakuma additionally teaches culturing Fuscoporia in white birch trunks (which contain white birch sap) (Artificial inoculation method of F. oblique in a Birch).

Although Sakuma does not specifically teach the claimed wood constituents were used, or that the hyphae were exposed to light during culture, Sakuma does teach the method wherein birch wood is used in culturing the Fuscoporia. Since birch wood and saw dust inherently contains the claimed constituents, the method of Sakuma must also inherently include the

claimed constituents in the culture methods. In addition, Sakuma teaches the Fuscoporia hyphae grow on trunks of birches (Summary of Invention) and that the culture methods of the invention also include growing hyphae on birch trunks (Artificial Inoculation Method of Fuscoporia oblique in a Birch), which must also necessarily be exposed to light during growth.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 – 2 and 4 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma in view of Kerwin et al. (Applied Micro., 1969).

Applicant claims a method for culturing Kabanoanatake in liquid, the method consisting of inoculating seed fungi from cultured Kabanoanatake in a liquid medium; wherein the medium contains a mixture of malt, glucose, saccharose or starch, peptone, yeast extract, water and phosphate buffer; and incubating the culture at 20 – 30C for 20 – 49 days, or 100 or more days; and obtaining active ingredients from the hyphae or medium. The active ingredients are contained in the medium, which is composed of 10g malt extract, 10g glucose, 3g peptone and 3g yeast extract per liter of medium; white birch sap is used instead of or in addition to water in the medium; the medium further contains one or more wood constituents which is selected from a disclosed group; the wood constituents are included at 0.00001 – 0.00075%, or at 0.000293%. The method further comprises determining the time of formation of active ingredients, based on culture color, protein amounts in the medium, decrease in carbon sources, pH of the medium; and collecting the active ingredients. The culture is a shake culture using a jar fermenter and the method further comprises exposing growing hyphae to light.

Sakuma teaches a method for culturing Fuscoporia oblique (Kabanoanatake), the method comprising inoculating Fuscoporia into a liquid medium comprising malt, glucose, saccharose, starch, peptone, yeast extract, water, and phosphate buffer, white birch saw dust (or wood

constituents) (Culture Improvements). The hyphae and/or medium were then extracted for active ingredients (culture improvements). Sakuma teaches that culturing of Fuscoporia is optimal at 13 – 30C for up to 4 months (Artificial Culture of the Hypha of F. oblique). Sakuma additionally teaches culturing Fuscoporia in white birch trunks (which contain white birch sap) (Artificial inoculation method of F. oblique in a Birch).

Although Sakuma does not specifically teach the claimed wood constituents were used, or that the hyphae were exposed to light during culture, Sakuma does teach the method wherein birch wood is used in culturing the Fuscoporia. Since birch wood and saw dust inherently contains the claimed constituents, the method of Sakuma must also inherently include the claimed constituents in the culture methods. In addition, Sakuma teaches the Fuscoporia hyphae grow on trunks of birches (Summary of Invention) and that the culture methods of the invention also include growing hyphae on birch trunks (Artificial Inoculation Method of Fuscoporia oblique in a Birch), which must also necessarily be exposed to light during growth.

Sakuma does not teach the method wherein the medium contains the claimed amounts of each component, or wherein the culture is a shake culture using a jar fermenter. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine practice and experimentation. It would have been further obvious to one of ordinary skill in the art to use a shake culture and jar fermenter, since they were routinely used in the art for culturing fungi. In support, Kerwin teaches growing basidiomycetes in liquid mediums comprising glucose, maltose, peptone, phosphate buffers and malt, wherein the amounts of each ingredient are variable (Table 1, p.348). Kerwin additionally teaches the cultures are shake cultures in jar

fermenters (p.347). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice, as evidenced by Kerwin, to optimize the amounts of components in the culture of Sakuma, as well as to use a jar fermenter in a shake culture, with a reasonable expectation for successfully culturing the Fuscoporia (or Basidiomycete) of Sakuma.

11. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma in view of Wetzstein et al. (Applied and Environ Micro, 1999).

Applicant claims a method for culturing Kabanoanatake in liquid, the method consisting of inoculating seed fungi from cultured Kabanoanatake in a liquid medium; wherein the medium contains a mixture of malt, glucose, saccharose or starch, peptone, yeast extract, water and phosphate buffer; and incubating the culture at 20 – 30C for 20 – 49 days, or 100 or more days; and obtaining active ingredients from the hyphae or medium. The medium additionally contains humic acid.

Sakuma teaches a method for culturing Fuscoporia oblique (Kabanoanatake), the method comprising inoculating Fuscoporia into a liquid medium comprising malt, glucose, saccharose, starch, peptone, yeast extract, water, and phosphate buffer, white birch saw dust (or wood constituents) (Culture Improvements). The hyphae and/or medium were then extracted for active ingredients (culture improvements). Sakuma teaches that culturing of Fuscoporia is optimal at 13 – 30C for up to 4 months (Artificial Culture of the Hypha of F. oblique).

Sakuma does not teach the method wherein the culture medium further comprises humic acid. However, at the time of the claimed invention, it was well known in the art that

Basiodiomycetes were commonly grown in humus (or humic acid). In support, Wetzstein teaches methods of culturing various Basidiomycetes, wherein the culture medium is humus, or contains humus (or humic acid) (abstract, p.1156-1157). At the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to include humus, or humic acid in mediums for Basidiomycetes, and in practicing the culture methods of Sakuma, since it was a well known habitat of such fungi, as evidenced by Wetzstein. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practices and Wetzstein to include humus or humic acid in the medium of Sakuma, with a reasonable expectation for successfully culturing the Basidiomycetes, Fuscporia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
March 1, 2005
AU 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER